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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,767	08/22/2001	Paul A Moore	PZ007P2	7025

22195 7590 06/21/2005

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,767	NI ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-26,29-37 and 40-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-26,29-37 and 40-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the papers filed 20 April 2005, the inventorship in this nonprovisional application has been changed by the deletion of:

BREWER, Laurie A.

CARTER, Kenneth C.

LAFLEUR, David W.

DILLON, Patrick J.

EBNER, Reinhard

ENDRESS, Gregory A.

FAN, Ping

FENG, Ping

FERRIE, Ann M.

FISCHER, Carrie L.

FLORENCE, Charles

FLORENCE, Kimberly A.

GREENE, John M.

OLSEN, Henrik S.

KYAW, Hla

LI, Yi

NI, Jian

YOUNG, Paul E.

SHI, Yanggu

SOPPET, Daniel R.

WEI, Ying-Fei

YU, Guo-Liang

ZENG, Zhizhen.

2. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Specification

3. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

> The entire disclosure of each document cited (including patents, patent applications, journal articles, abstracts, laboratory manuals, books, or other disclosures) in the Background of the Invention, Detailed Description, and Examples is hereby incorporated herein by reference. Further, the hard copy of the sequence listing submitted herewith and the corresponding computer readable form are both incorporated herein by reference in their entireties. Additionally, the specifications and sequence listings of International Application No. PCT/US01/05614 filed February 21, 2001, and of U.S. Provisional Applications Serial Nos. 60/184,836 and 60/193,170 are all hereby incorporated by reference in their entirety.

4. Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth In *Ex parte* Raible, 8 USPQ2d 1707, (BPAI, 1998)

> The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree
>
> * * *
>
> We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky , 474 F.2d 671, 177 USPQ 144 , (CCPA 1973).

5. Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

6. At pages 7-8 of the response received 20 April 2005, hereinafter the response, argument is presented that the statement of incorporation is appropriate and the objection should be withdrawn.

7. While applicant has different intent or purposes in incorporating different documents, the variances in intent does not lessen the need of applicant to indicate why each of the documents are being relied upon and where that pertinent information is found in each. By applicant having claimed benefit or priority in their declaration, such benefit is granted automatically to the extent that material found in the present application is also found in the priority document.

8. To the extent that applicant seeks to incorporate documents for their disclosure of non-essential subject matter, the simple listing of the documents can be relied upon for establishing the level of skill in the art and that which was well known and as such do not need to be brought in or even disclosed in the present application. Again, such benefit is derived without incorporating the documents. In the present case, however, the specification indicates that applicant is seeking to incorporate virtually any and every document identified in the disclosure, yet does not identify why each of the documents is being relied upon and where the pertinent information is to be found. Accordingly, to the extent that applicant has retained language in the specification stipulating that the various documents have been incorporate by reference, the objection is maintained.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 24-26, 29-37, and 40-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

11. For convenience, claim 24 is reproduced below.

24. (Currently Amended) A method of diagnosing pancreatic cancer comprising:

(a) contacting a pancreatic biological sample from a test subject with an antibody or fragment thereof that specifically binds a protein whose amino acid sequence consists of amino acid residues 1 to 201 of SEQ ID NO:344;

(b) assaying the level of said protein in the pancreatic biological sample; and

(c) comparing the level of said protein in the pancreatic biological sample with the ~~a standard~~ level of said protein in a non-cancerous pancreatic biological sample;

whereby an increase in the level of said protein in the pancreatic biological sample compared to the ~~standard~~ level of said protein in a non-cancerous pancreatic biological sample is indicative of pancreatic cancer.

12. As presently worded, the claim has been interpreted and requiring the use of "an antibody or fragment thereof that binds to a protein whose amino acid sequence consists of amino acid residues 1 to 201 of SEQ ID NO: 344," and wherein the level of "the protein" is increased in cancerous tissue over that of non-cancerous pancreatic tissue. Or to restate the claim, the protein to which the antibody binds must also be present in the sample, and that said protein cannot have any change in its amino acid sequence.

13. A review of the disclosure finds but a single instance where SEQ ID NO: 344 is even made, and then said occurrence is to be located at page 223, last two lines, where "predicted epitopes" of SEQ ID NO: 344 are suggested. A review of the disclosure fails to identify where SEQ ID NO: 344 has been correlated with any disease, including pancreatic cancer. Page 23, lines 14-15, teach gene 96 "is expressed primarily in pancreatic tumor and ulcerative colitis, and to a lesser extent in several tumors and normal tissue." A review of the disclosure finds the term "pancreatic cancer" has been used at the following occasions: Page 610, lines 5 and 12; page 613, line 29; page 614, line 24; page 635, page 31; page 636, line 25. At no time is the term used in conjunction with SEQ ID NO: 344.

14. In accordance with claims 24 and 35, one is to compare the level of the protein to a "standard level of the protein." A review of the specification fails to identify what the standard level of the protein is. Additionally, one is to use antibodies, or parts thereof, in the assay; however, the specification fails to teach in such full, clear, and concise language that any such antibody, antibody fragment (human, polyclonal, or chimeric; Fab fragment, single chain, etc.) has been developed and found useful in practicing the claimed method.

15. In accordance with claim 32-34 and 40-45, the antibody is to be labeled. Again as noted above, the specification does not provide an adequate written description of the antibodies, much less claimed labeled versions of same, which have been found useful in the claimed invention. Assuming arguendo, that the antibodies have been adequately described, a position the Office does not concede, the specification is essentially silent as to what constitutes normal or standard levels of the protein in the myriad sample types encompassed by the claimed method.

16. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

17. To the extent that claim 35 is directed to a method limited in that one is to analyze the level of a protein encoded by ATCC Deposit No. 209082, the specification does not provide an adequate written description of the deposit which reasonably suggests that the nucleic acid in the vector is in proper reading order, that the protein has been expressed by any cell comprising said vector. Additionally, said deposit is described in Table 1 as comprising a nucleotide sequence of some 1705 nucleotides, which, if in proper coding sequence, would encode a sequence of some 568 amino acids, yet as seen in Table 1 at page 467, the purported amino acid sequence is but 344 residues in length. Such discrepancies speak to the vector and its inherent insert not being

capable of encoding any amino acid in its present case, and a review of the disclosure fails to find where any such protein has been expressed from same, much less determine what constitutes normal and disease-indicating levels of same in any sample fro any subject, where the subject being tested can be any life form that has a pancreas.

18. For the above reasons, and in the absence of convincing evidence to the contrary, claims 24-26, 29-37, and 40-45 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Response to argument

19. At page 9 of the response applicant asserts that the specification provides an adequate written description of the protein corresponding to SEQ ID NO: 344, directing attention to page 488 of the specification. For convenience, the noted paragraph on page 488 is reproduced below.

> **Table 1 summarizes the information corresponding to each "Gene No." described above. The nucleotide sequence identified as "NT SEQ ID NO:X" was assembled from partially homologous ("overlapping") sequences obtained from the "cDNA clone ID" identified in Table 1 and, in some cases, from additional related DNA clones. The overlapping sequences were assembled into a single contiguous sequence of high redundancy (usually three to five overlapping sequences at each nucleotide position), resulting in a final sequence identified as SEQ ID NO:X.**

20. Argument is presented that the SEQ ID NO: 344 corresponds to Gene No.: 96, and that page 222 of the disclosure provides a description of Gene No.: 96. For convenience, the relevant portion of page 22 is reproduced below.

FEATURES OF PROTEIN ENCODED BY GENE NO: 96

The translation product of this gene is homologous to the Clostridium perfringens enterotoxin (CPE) receptor gene product and shares sequence homology with a human ORF specific to prostate and a glycoprotein specific to oligodendrocytes, both of which are tissue specific proteins. See e.g., Katahira et al. J Cell Biol. 136(6):1239-1247 (1997). PMID: 9087440; UI: 97242441.

The above argument has not been found persuasive towards the withdrawal of the rejection, as the claimed protein is not the same as that found in bacteria. The claimed method stipulates that the protein must have a precise amino acid structure. The record indicates, however, that the amino acid sequence is deduced from overlapping cDNA sequences. The aspect of using cDNA speaks to the prior elimination of intervening sequences, or introns, as well as promoter regions. In short, the sequence used to deduce the amino acid sequence now recited was not deduced from any gene, but rather from cDNA fragments. The record does not provide a full clear and concise description of the full amino acid sequence of the actual protein, but rather, provides at best a partial sequence of such a protein. In support of this position attention is directed to the above-identified publication of Katahira et al. As stated therein on page 1239, left column of abstract:

Vero cells. The nucleotide sequence of *CPE-R* showed that the enterotoxin receptor consists of 209 amino acids with a calculated molecular mass of 22,029 D. This

It is noted with particularity that SEQ ID NO: 344 is shown to comprise 201 amino acids. Given this contrast in lengths, the claimed method clearly requires one to perform the diagnosis on the basis of a fragmented polypeptide. The specification does not provide an adequate written

description of antibodies that would recognize the fragment over that of the full-length polypeptide. Furthermore, the specification does not provide any indication as to just what the missing amino acids are so that one would be able to identify antibodies that recognize one peptide over that of another.

21. At pages 10-11 of the response argument is presented that the claimed method is adequately described and enabled as a result of amendments to claim 24 and 35 wherein the tem "standard" has been removed.

22. The above argument has not been found persuasive and that the amendment has caused new grounds under 12, second paragraph, to be made in the instant Office action, *infra*. Using claim 24 as an example, the method requires one to measure both "non-cancerous pancreatic tissue" and "pancreatic biological sample" and to detect an increase of said protein in the second over that of the prior. The specification is silent as to how one is to take into consideration actors such as age, gender, race, medications (e.g., chemotherapy), other diseases, (e.g., diabetes), etc. that could all affect the level of protein production in "non-cancerous pancreatic tissue."

23. While argument is presented that one of skill in the art could determine the normal level, the claimed method presupposes that one knows just what is a normal level, even with extenuating factors, and that this level of protein production, which can be determined independently from the other part of the assay, is to used in comparing the amount of protein present (not increased) in the sample. The specification, as noted above, is silent as to what are normal vales and what are cancerous levels of this protein, yet this relationship is critical to the claimed method. The failure of the specification to provide a full, clear, and concise description

of the claimed method also fails to reasonably suggest that applicant was in possession of the invention at the time of filing.

24. At page 12 of the response argument is presented that one of skill in the art would, after considering the disclosure, reach the conclusion that the deposited construct does encode a polypeptide. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

25. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

26. Claims 24-26, 29-37, and 40-45 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' "

> *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

27. It is well settled that one cannot enable that which they do not yet possess. As presented above, the specification does not reasonably suggest that applicant was in the possession of the requisite knowledge of normal and disease-indicating levels of the protein corresponding to SEQ ID NO: 344, and the specification does not reasonably suggest that applicant was in possession of the requisite reagents, e.g., antibodies or fragments of same, and the various labeled embodiments. In view of such failure to reasonably suggest that applicant was in possession of the invention at the time of filing, the same specification has not been found to fully enable the claimed invention. Therefore, and in the absence of convincing evidence to the contrary, claims 24-26, 29-37, and 40-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

28. As presented above, the specification has not been found to set forth the reaction conditions and essential starting materials under which the claimed method is to be practiced. Furthermore, the documents cited within the body of the disclosure that go to teach various aspects of the invention have not been properly incorporated by reference and cannot now be relied upon by applicant to fulfill the enablement requirement of 35 USC 112, first paragraph. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the

> specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

29. Therefore, and in the absence of convincing evidence to the contrary, claims 24-26, 29-37, and 40-45 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Response to argument

30. At pages 13-15 argument is presented that one of skill in the art would have recognized, or been able to perform various aspects of the invention without any further disclosure. These arguments, like that above, appear to be that of applicant's representative and are not supported by any evidentiary showing. See MPEP 2145. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

31. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

32. Claims 24-26, 29-37, and 40-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

33. Claims 24 and 35 recite the limitation "the level of said protein in a non-cancerous pancreatic biological sample" in step (c). There is insufficient antecedent basis for this limitation in the claims. Claims 25, 26, 29-34, 36, 37, and 40-45, which depend therefrom, fails to overcome this issue and are similarly rejected.

Conclusion

34. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

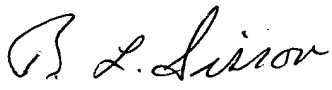
36. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

39. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
17 June 2005